

**REMARKS**

Claim 1 has been amended to recite "consisting essentially of" language to exclude components which materially affect the basic and novel characteristic(s) of the claimed invention. In this regard, Applicants submit that an amphipathic polymer (i.e., an amphiphilic polymer) materially affects a basic and novel characteristic of the claimed invention, as can be seen from the experimental evidence set forth in the present application. For instance, as disclosed at page 12, lines 21-25 in the specification, the presence of an amphipathic polymer in a comparative embodiment resulted in a lower metabolic activity as compared with an invention embodiment which did not include an amphipathic polymer. A similar result can be seen in the first paragraph on page 14 in the specification. Also, Applicants note that the present application refers to prior art that includes an amphipathic polymer for preparing a honeycomb structure.

Claim 17 has been added corresponding to the version of claim 1 prior to the above amendment, except for reciting that no amphipathic polymer is present. As discussed above, the disclosure at page 12, lines 21-25 in the specification indicates the presence of an amphipathic polymer in a comparative embodiment resulted in a lower metabolic activity as compared with an invention embodiment which did not include an amphipathic polymer, and a similar result can be seen in the first paragraph on page 14 in the specification. Also, Applicants note that the present application refers to prior art that includes an amphipathic polymer for preparing a honeycomb structure. Thus, Applicants submit that one of ordinary skill in the art would recognize that no amphipathic polymer is present in Applicants' invention

Entry of the above amendment is respectfully requested.

**Information Disclosure Statement Issues**

(1) Applicants note that on the PTO/SB/08 form attached to the Office Action, the Examiner has neither initialed nor lined through the citation of U.S. Patent 5,716,413, nor has any reason been give as to why that citation has neither been initialed nor lined through. Accordingly, Applicants respectfully request that the Examiner consider U.S. Patent 5,716,413 and return a copy of the PTO/SB/08 form with that citation initialed.

(2) On page 2 of the Office Action, the Examiner indicates that the information disclosure statement filed June 23, 2009, fails to comply with 37 CFR 1.98(a)(3)(ii), which requires a copy of the translation if a written English-language translation of a non-English-language document, or portion thereof, is within the possession, custody, or control of, or is readily available to any individual designated in § 1.56(c). The Examiner indicates that it has been placed in the application file, but the information referred to therein has not been fully considered, since the publication by Sato et al. is in the Japanese language.

In response, Applicants note that simply because the publication by Sato et al. is in the Japanese language does not mean that it should not be considered by the Examiner. Applicants note that MPEP 609.04(a), subsection III., states that:

Each information disclosure statement must further include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information listed that is not in the English language. ...

Where the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting

an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report.

(emphasis in original). Since the Sato publication was cited in a European Search Report in the counterpart European application, and since the European Search Report includes an "A" indication in connection with the Sato publication, Applicants submit that the Sato publication should be considered by the Examiner.

Further in this regard, Applicants note that MPEP 609.05(b) states that:

Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted (see MPEP § 609.04(a), subsection III.) and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches. The examiner need not have the information translated unless it appears to be necessary to do so. The examiner will indicate that the non-English language information has been considered in the same manner as consideration is indicated for information submitted in English. The examiner should not require that a translation be filed by applicant.

Since the MPEP indicates that the Sato reference should be considered in view of the concise explanation submitted (the indication in the European Search Report) and that the Examiner should not require a translation to be filed by Applicants, the Examiner is respectfully requested to return a copy of the PTO/SB/08 form with Sato citation initialed.

### **Obviousness Rejections**

On page 2 of the Office Action, claims 1, 3, 4, 8-10 and 12 are newly rejected under 35 U.S.C. §103(a) as being unpatentable over Nishikawa et al. (Mat. Res. Soc. Symp. Proc. 724:N11.7.1-N11.7.6; 2002), in view of Watanabe et al. (Biomacromolecules 3:1109- 1114; 2002), and further in view of Sawhney, A. (U.S. Patent No.: 6,818,018; filed Aug. 14, 1998). On page 5 of the Office Action, claims 1, 6 and 16 are newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Nishikawa et al. (Mat. Res. Soc. Symp. Proc. 724:N11.7.1-N11.7.6; 2002), in view of Watanabe et al. (Biomacromolecules 3:1109- 1114; 2002), and further in view of Sawhney, A. (U.S. Patent No.: 6,818,018; filed Aug. 14, 1998), as applied to claims 1, 3, 4, 8-10 and 12, and further in view of Zou et al. (U.S. Patent Publication No.: 2002/0187105; filed Feb. 1, 2002).

In response, Applicants note initially that the Examiner indicates "the instant claims do not exclude the presence of amphiphilic polymers in the tissue regeneration substrate. ... Thus, while the substrate polymer is primarily polylactic acid, it may include additional elements such as amphiphilic polymers."

Further, to distinguish over the cited art more clearly, Applicants have amended the claims so that they do not include any amphiphilic copolymer as recited above.

Thus, Applicants submit that a distinguishing technical feature of the present invention lies in the finding that a honeycomb structure can also be prepared from non-amphiphilic polymer if a phospholipid, which is a low molecular weight compound, is added.

Applicants submit that within the technical level of the prior art, an amphiphilic polymer or polycationic polymer was crucial for preparing a honeycomb structure. However, according

to the present invention, a honeycomb structure can be formed even from hydrophobic polymers such as polylactic acid as long as a phospholipid is added.

Accordingly, Applicants submit that the present invention is not obvious over the cited art, and withdrawal of these rejections is respectfully requested.

### **Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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